

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM11/0707

LUCY J BILLINGS INCYTE PHARMACEUTICALS INC 3174 PORTER DRIVE PALO ALTO CA 94304

APPLI	CATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT		DATE MAILED
	09/007,306	01/15/98	002	NASHED, N	1652	07/07/98
First Named Applicant	11T1 1 M/A 81					

TITLE OF INVESTIGATION NOVEL GUANOSINE MONOPHOSPHATE REDUCTASE

ATTY'S DOCKET NO.	CLASS-SUBCLASS BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 PF-0182-	1 424-094.400	G26 UTIL	.ITY NO	\$1320.0	0 10/07/98

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

- I. Review the SMALL ENTITY status shown above.

 If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
 - A If the status is changed, pay twice the amount of the EEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
 - B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.
- II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give application number and batch number.

 Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

Notice of Allowability

Application No.

09/007,306

Applicant(s)

Hellman, J. L.

Examiner

Nashaat T. Nashed

Group Art Unit 1652



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.
∑ This communication is responsive to <u>communication filed January 15, 1998</u> .
∑ The allowed claim(s) is/are 1 and 11
The drawings filed on are acceptable.
☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
received.
received in Application No. (Series Code/Serial Number)
\square received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
*Certified copies not received:
☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).
☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
Applicant MUST submit NEW FORMAL DRAWINGS
because the originally filed drawings were declared by applicant to be informal.
including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No
including changes required by the proposed drawing correction filed on, which has been approved by the examiner.
☐ including changes required by the attached Examiner's Amendment/Comment.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal lettter addressed to the Official Draftsperson.
☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.
Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.
Attachment(s)
☐ Notice of References Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s)5
☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
Notice of Informal Patent Application, PTO-152
☐ Interview Summary, PTO-413
⊠ Examiner's Amendment/Comment
Examiner's Comment Regarding Requirement for Deposit of Biological Material

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1652.

The application has been amended as requested in the communication filed January 15, 1998. Claims 2-10 have been canceled, claims 11-14 have been amended and claims 1, 11-19 are pending in this Office action.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I	Claims 1 and 11, drawn to the guanosine monophosphate reductase (GMPR) of SEQ ID NO: 1, classified in Class 435,
Group II	subclass 189. Claim 12, drawn to antibodies raised against the GMPR of
Group III	SEQ ID NO: 1, classified in Class 530, subclass 397.1. Claim 13, drawn to agonist of the biological activity of GMPR and methods of their use, classification unknown as the specification discloses no structural information for the claimed compound(s). Possible classifications could be Class 260 (organic compounds), Class 530 (peptide and proteins), Class 536 (carbohydrates), Class 423 (inorganic compounds), etc.
Group IV	Claims 14 and 15, drawn to antagonist of the biological activity of GMPR and methods of their use, classification unknown as the specification discloses no structural information for the claimed compound(s). Possible classifications could be Class 260 (organic compounds), Class 530 (peptide and proteins), Class 536 (carbohydrates), Class 423 (inorganic compounds), etc.
Group V	claim 16, drawn to a method of treating cancer, unknown classification, see above.
Group VI	claim 17, drawn to a method of treating viral diseases, unknown classification, see above.
Group VII	claim 18, drawn to a method of treating inflammatory diseases, unknown classification, see above.
Group VIII	claim 19, drawn to a method of treating immunological disorder, unknown classification, see above.

The inventions are distinct, each from the other because of the following reasons:

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The GMPR of Group I, the antibody of Group II, the agonist of Group III and the antagonist of Group IV are independent chemical entities and require different literature searches.

Inventions of Group I and those of Groups V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the enzyme of Group I is not disclosed as used in the methods for treating cancer of Group V, viral diseases of Group VI, inflammatory diseases of Group VIII or the immunological disorder of Group VIII.

Inventions of Group II and those of Groups V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibody of Group II is not disclosed as used in the methods for treating cancer of Group V, viral diseases of Group VI, inflammatory diseases of Group VIII or the immunological disorder of Group VIII.

Inventions of Group III and those of Groups V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the agonist of Group II is not disclosed as used in the methods for treating cancer of Group V, viral diseases of Group VI, inflammatory diseases of Group VIII or the immunological disorder of Group VIII.

Inventions IV and those of Groups V-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of treatment of cancer of Group V, the viral diseases of Group VI, inflammatory diseases of Group VIII and the immunological disorder of Group VIII can be practiced with materially different products, whereas the product of Group IV can be used in different methods for the treatments of various diseases.

Inventions of Groups V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the various methods of treatments of Groups V-VIII are not disclosed as capable of use together and have different functions.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Sheela Mohan-Peterson on June 8, 1998 a provisional election was made with traverse to prosecute the invention of Group I, claims 1 and 11. Affirmation of this election must be made by applicant in responding to this Office action. Claims 12-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Examiner's Amendment:

- (1) Cancel non-elected claims 12-19.
- (2) In claim 1, line 2, insert "an enzymatically active" between "or" and "fragment".
- (3) In claim 11, line 2, insert "or an enzymatically active fragment thereof," after SEQ ID NO: 1.

Authorization for this examiner's amendment was given in a telephone interview with Sheela Mohan-Peterson on June 26, 1998.

Claims 1 and 11 are allowed.

The following is an examiner's statement of reasons for allowance: The applicant disclose a human gene having the nucleic acid sequence of SEQ ID NO: 2 which encodes a guanosine monophosphate reductase with the amino acid sequence of SEQ ID NO: 1. In this application, she claims the purified enzyme. Claims drawn to the nucleic acid sequences encoding the enzyme were found patentable in the parent case, i.e.,

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08/774,169, now U. S. Patent 5,756,332. Since the enzyme is also free from prior art of record, claims 1 and 11 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Wax, can be reached on (703) 308-4216. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert A. Wax
Supervisory Patent Examiner
Technology Center 1600